



Trends & Update

Distributor Conference

Indianapolis, IN May
10 & 11, 2016



The United States Department of Justice

Drug Enforcement Administration

James A. Arnold, Acting Chief
Liaison & Policy Section
Office of Diversion Control



Goals and Objectives

- Public Health Epidemic
- Impact on Society
- Drugs of Abuse
- The Controlled Substances Act: Checks & Balances
- Legal obligations: DEA registrant
- The DEA Response
- Drug Disposal
- Miscellaneous Topics

Public Health Epidemic



Public Health Epidemic

2000-2014 :

Unintentional drug overdose deaths in the US increased 137%, which was a 200% increase in overdose deaths involving opioids.

500,000 deaths due to prescription overdose

2015:

Over 47,000 drug-related overdose deaths

1 death every 11.16 minutes

46 deaths by end of an 8 hour work day

129 deaths every 24 hours

Public Health Epidemic

There were approximately 1½ times more drug overdose deaths in the United States than deaths from motor vehicle accidents.

In 2014, 28,647 of these deaths involved some type of opioid, including heroin.

In 2014, CDC indicates that there were about *19,000 "prescription opioid pain reliever deaths".

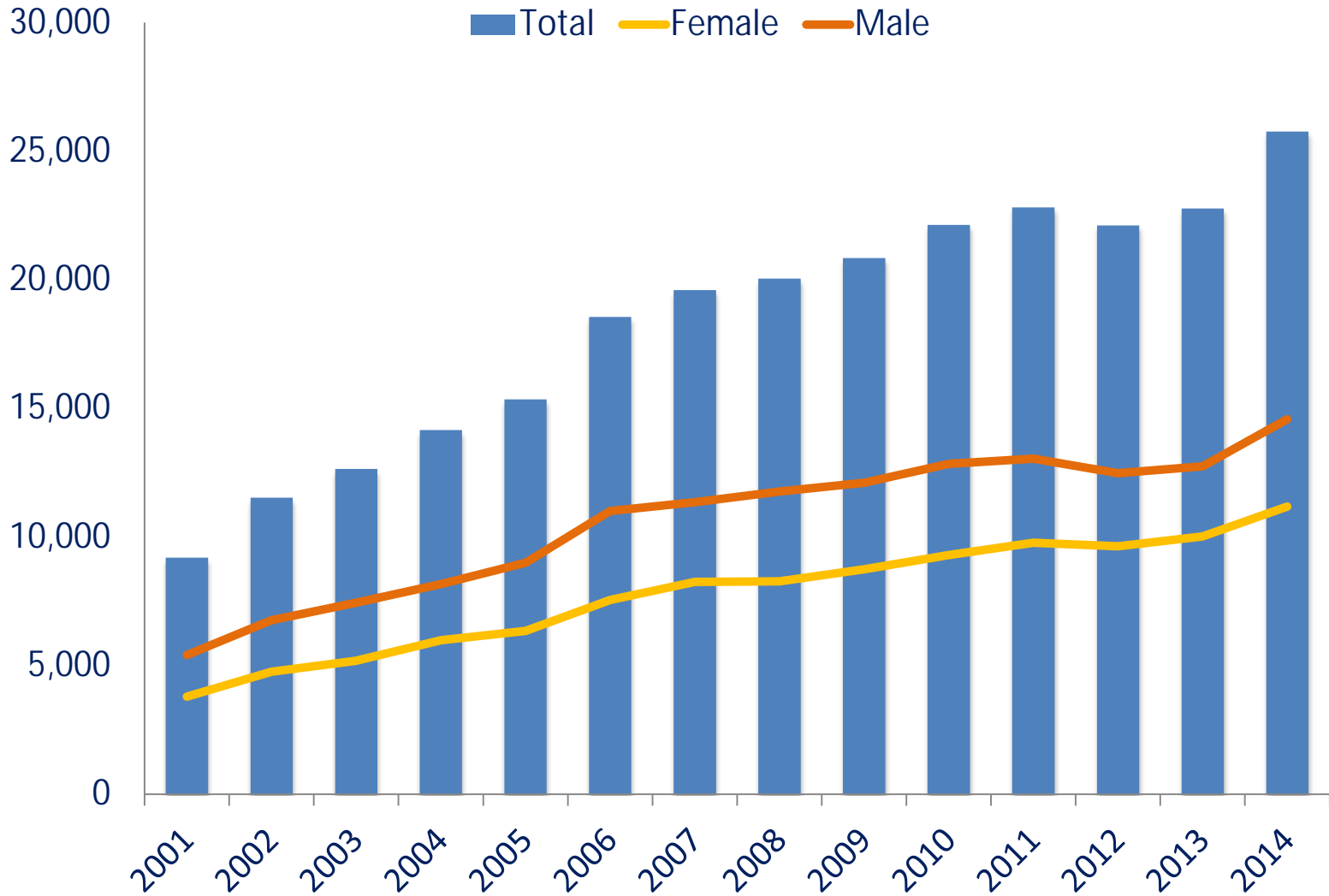
Prescription drug abuse is the fastest growing drug problem in the United States.

**Historically, CDC has programmatically characterized all opioid pain reliever deaths (natural and semisynthetic opioids, methadone, and other synthetic opioids) as "prescription" opioid overdoses. In 2014, a sharp increase in deaths involving synthetic opioids (other than methadone) coincided with law enforcement reports of increased availability of illicitly manufactured fentanyl, a synthetic opioid. However, illicitly manufactured fentanyl cannot be distinguished from prescription fentanyl in death certificate data.*



National Overdose Deaths

Number of Deaths from Prescription Drugs

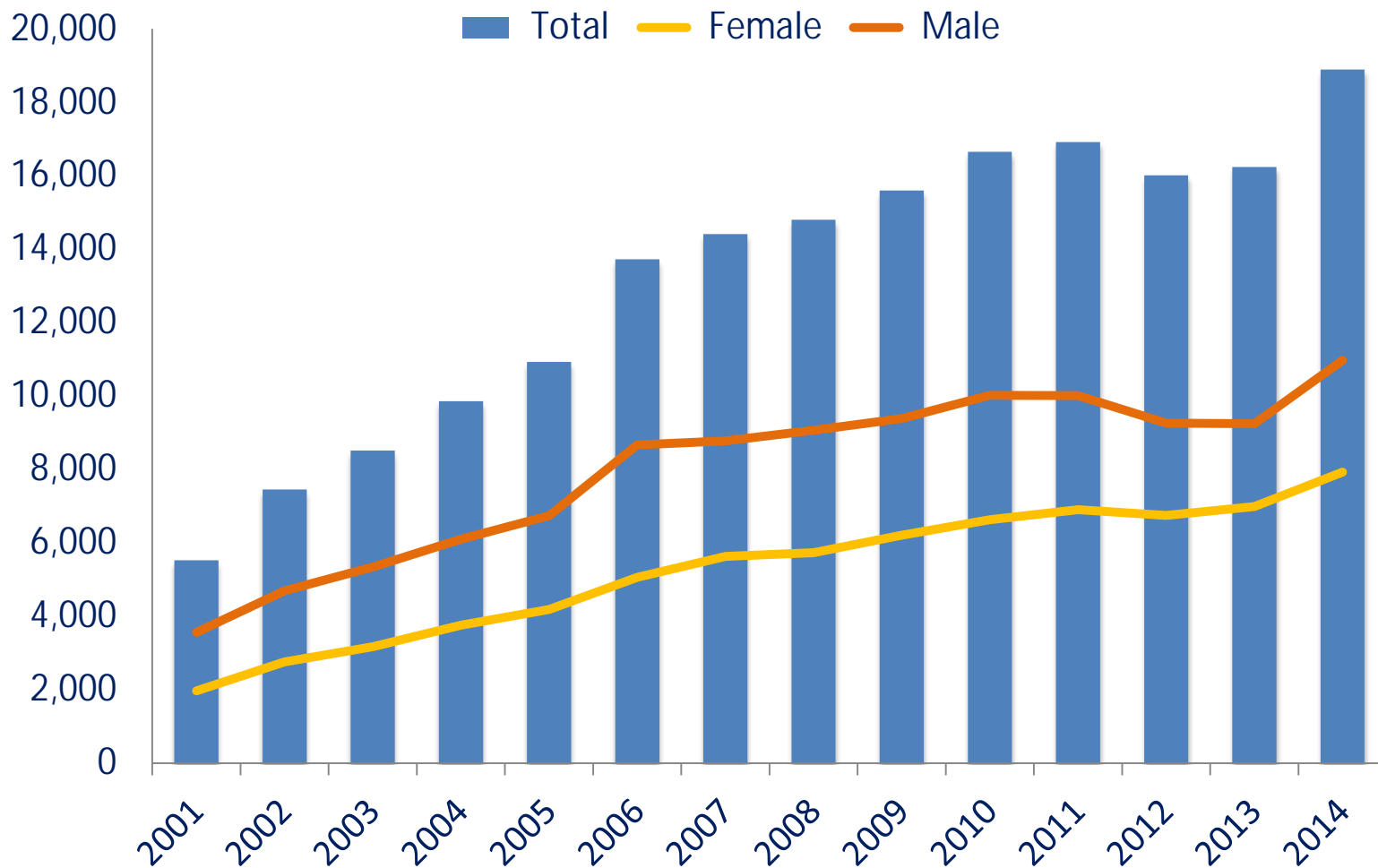


Source: National Center for Health Statistics, CDC Wonder



National Overdose Deaths

Number of Deaths from Prescription Opioid Pain Relievers

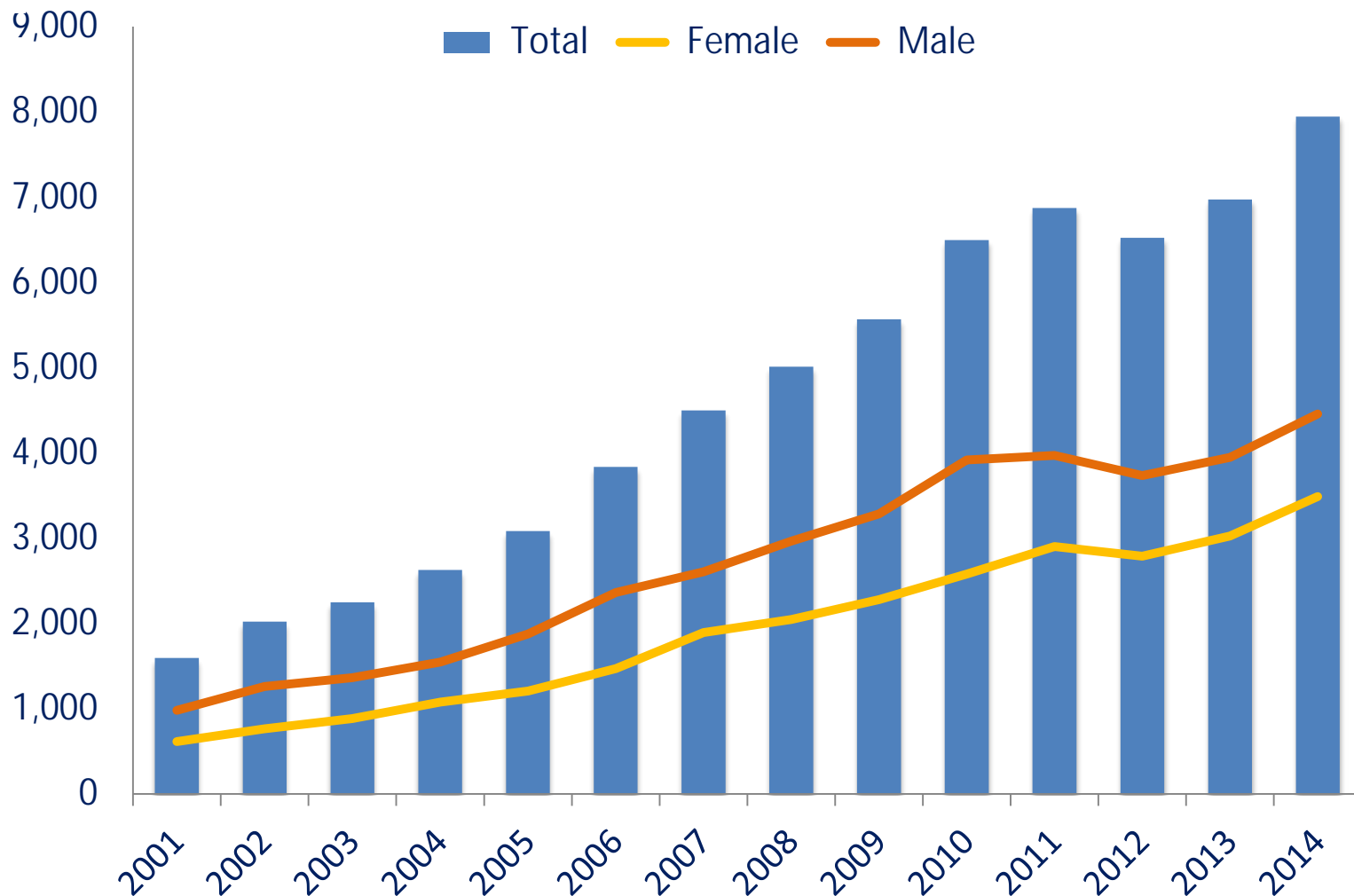


Source: National Center for Health Statistics, CDC Wonder



National Overdose Deaths

Number of Deaths from Benzodiazepines

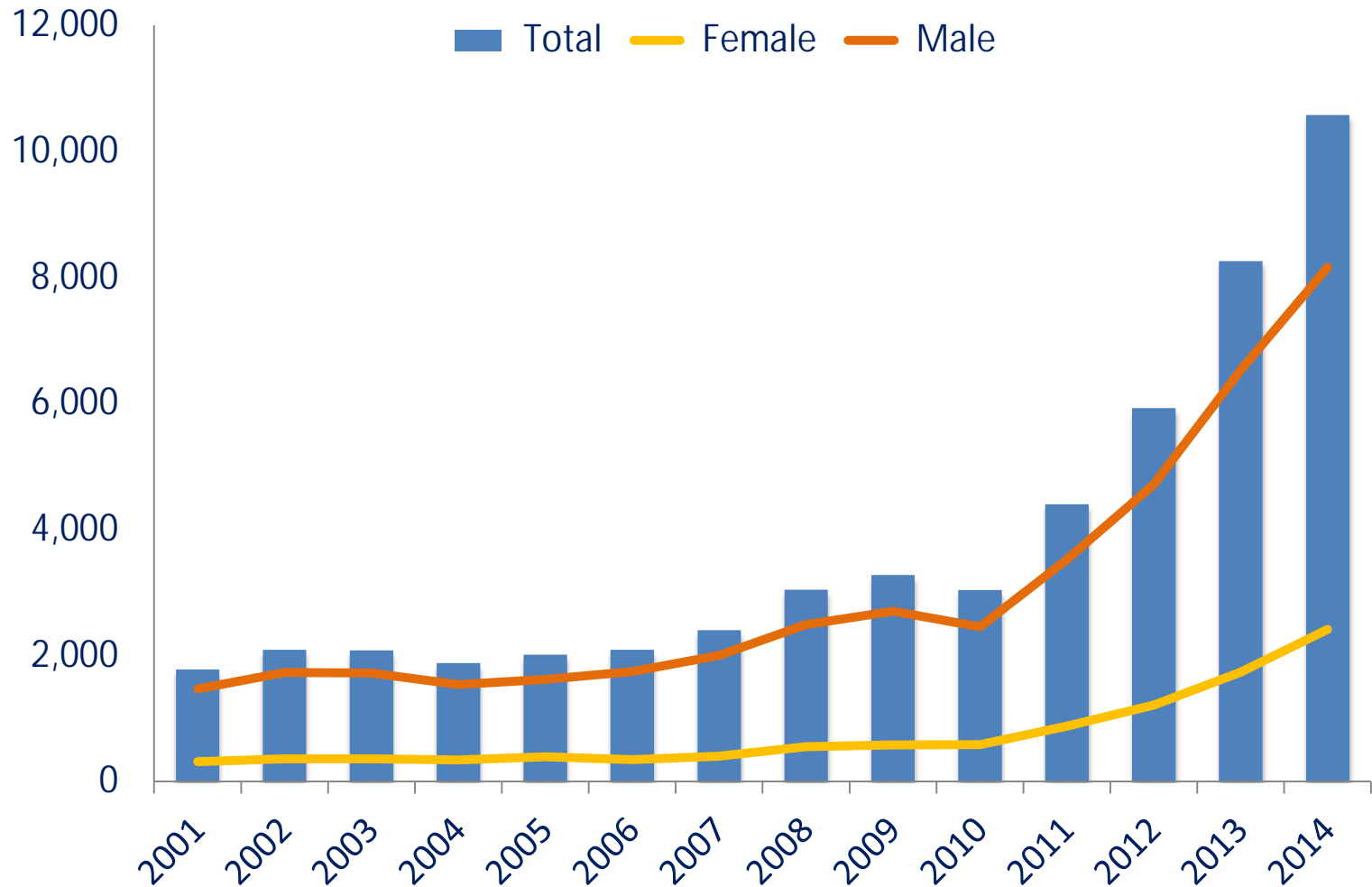


Source: National Center for Health Statistics, CDC Wonder



National Overdose Deaths

Number of Deaths from Heroin



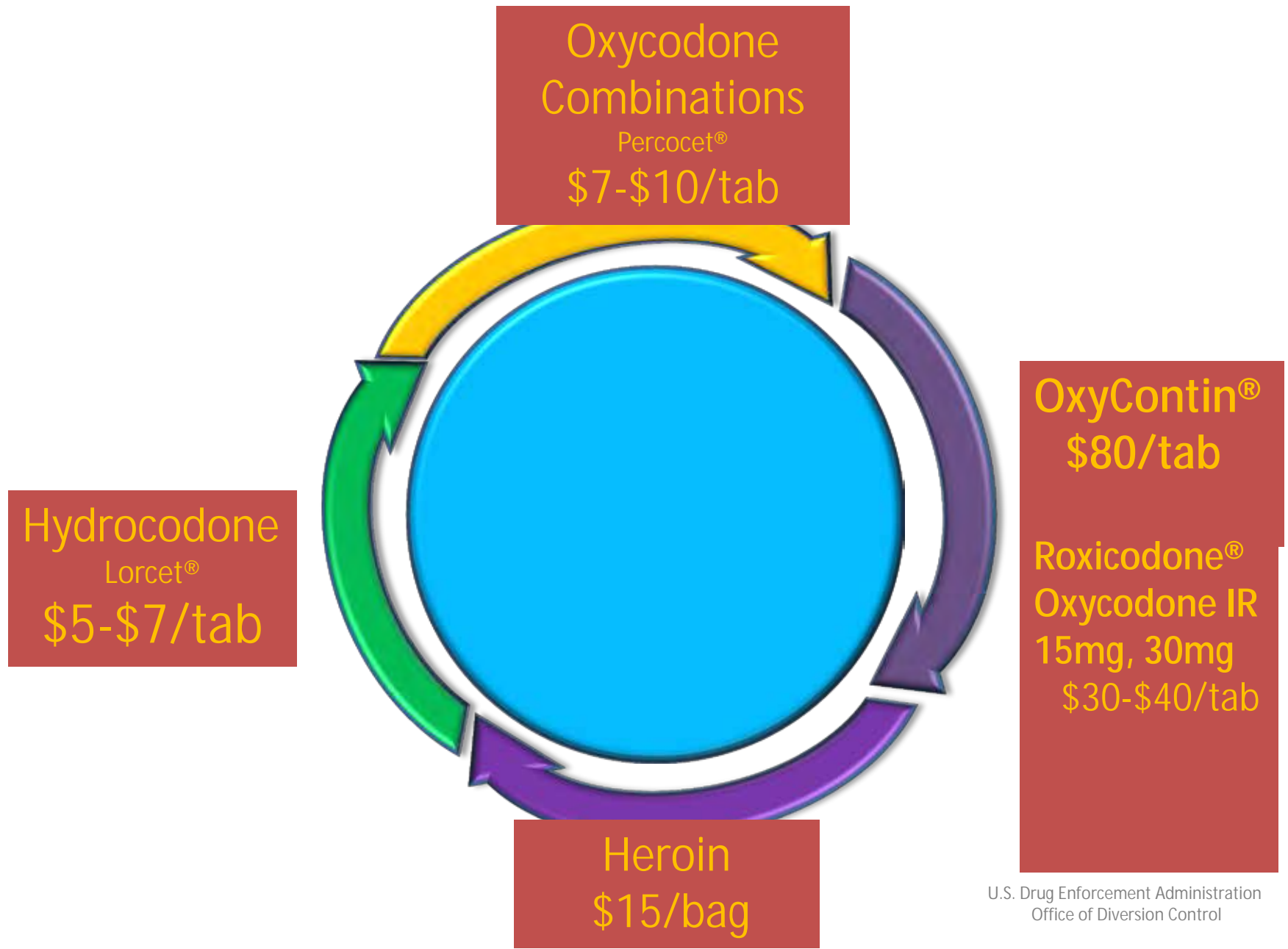
Source: National Center for Health Statistics, CDC Wonder



Prescription Opiates v. Heroin



Circle of Addiction & the Next Generation



Impact on Society



Chasing the Dragon

- The reality of the Opioid Epidemic and it's affect on the addict and loved ones.
- What Law Enforcement sees and deals with on a daily basis
- Warning: Strong language is used in this video, and some of the visuals maybe upsetting.

Drugs of Abuse



Hydrocodone

Ø Hydrocodone / Acetaminophen (toxicity)

Ø Similarities:

- Structurally related to codeine
- Equal to morphine in producing opiate-like effects

Ø Brand Names: Vicodin®, Lortab®, Lorcet®

Ø October 6, 2014 moved to SCHEDULE II

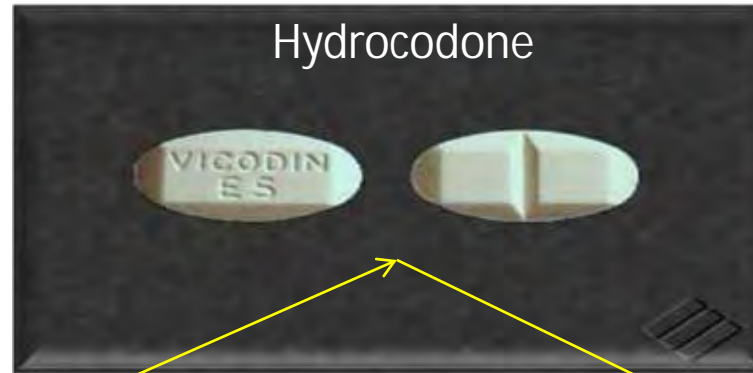
Ø "Cocktail" or "Trinity"

- Ø Hydrocodone
- Ø Soma® / carisoprodol
- Ø Alprazolam / Xanax®

Ø Street prices: \$2 to \$10+ per tablet depending on strength & region



The Trinity



Opiate



Muscle Relaxant



Benzodiazepine

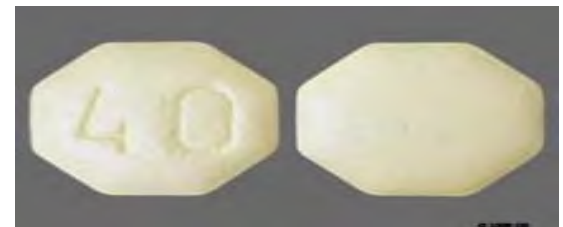
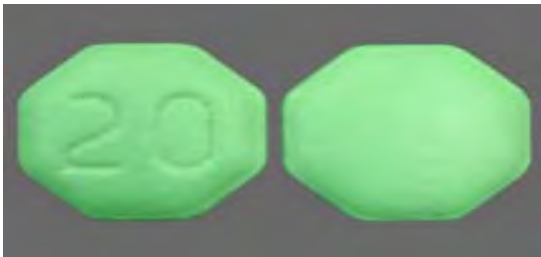
Oxycodone

- OxyContin controlled release formulation of Schedule II oxycodone
 - The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
 - Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
 - 10, 15, 20, 30, 40, 60, 80mg available
- Effects:
 - Similar to morphine in effects and potential for abuse/dependence
 - Sold in “Cocktails” or the “Holy Trinity”
 - Oxycodone, Soma[®] / Xanax[®]
- Street price: Approx. \$80 per 80mg tablet
- **NOTE: New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.**

Oxymorphone Extended Release Opana ER® (Schedule II)

Ø Opana ER® - (Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming popular and is abused in similar fashion to oxycodone ; August 2010 (Los Angeles FD TDS)
- Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
- Street: \$10.00 – \$80.00



Hydromorphone



Fentanyl



Fentora®



Actiq®

- Ø Fentanyl Patches
- Ø Fentanyl Citrate dispensed in a berry flavored lollipop-type unit
- Ø Fentanyl is 100 times more potent than morphine
- Ø Intended to be used for chronic cancer pain & only for people who are tolerant to prescription opioid (narcotic) pain medicines
- Ø Abused for its intense euphoric effects

Methadone- 5mg & 10mg



Methadone 40 mg



NDC 0406-0540-34

100 TABLETS

METHADOSE™
Dispersible Tablets **C II**
(Methadone Hydrochloride
Tablets for Oral Suspension USP)

40 mg

Each tablet contains:
Methadone Hydrochloride USP..... 40 mg
Rx only

Mallinckrodt

Usual Dosage:
See accompanying literature for dosage.

Keep tightly closed.

Dispense in a tight container (USP) with a child-resistant closure.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.,
Hazelwood, MO 63042 USA.

COVIDIEN™

The Controlled Substances Act: Checks & Balances



Mission

The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

while ...

ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical scientific needs, and



**DEA Registrants as
of 3/17/2016**

Importers 243

Manufacturers 548

Distributors 779

71,893 Pharmacies
1,506,344 Practitioners, MLP
16,858 Hospitals

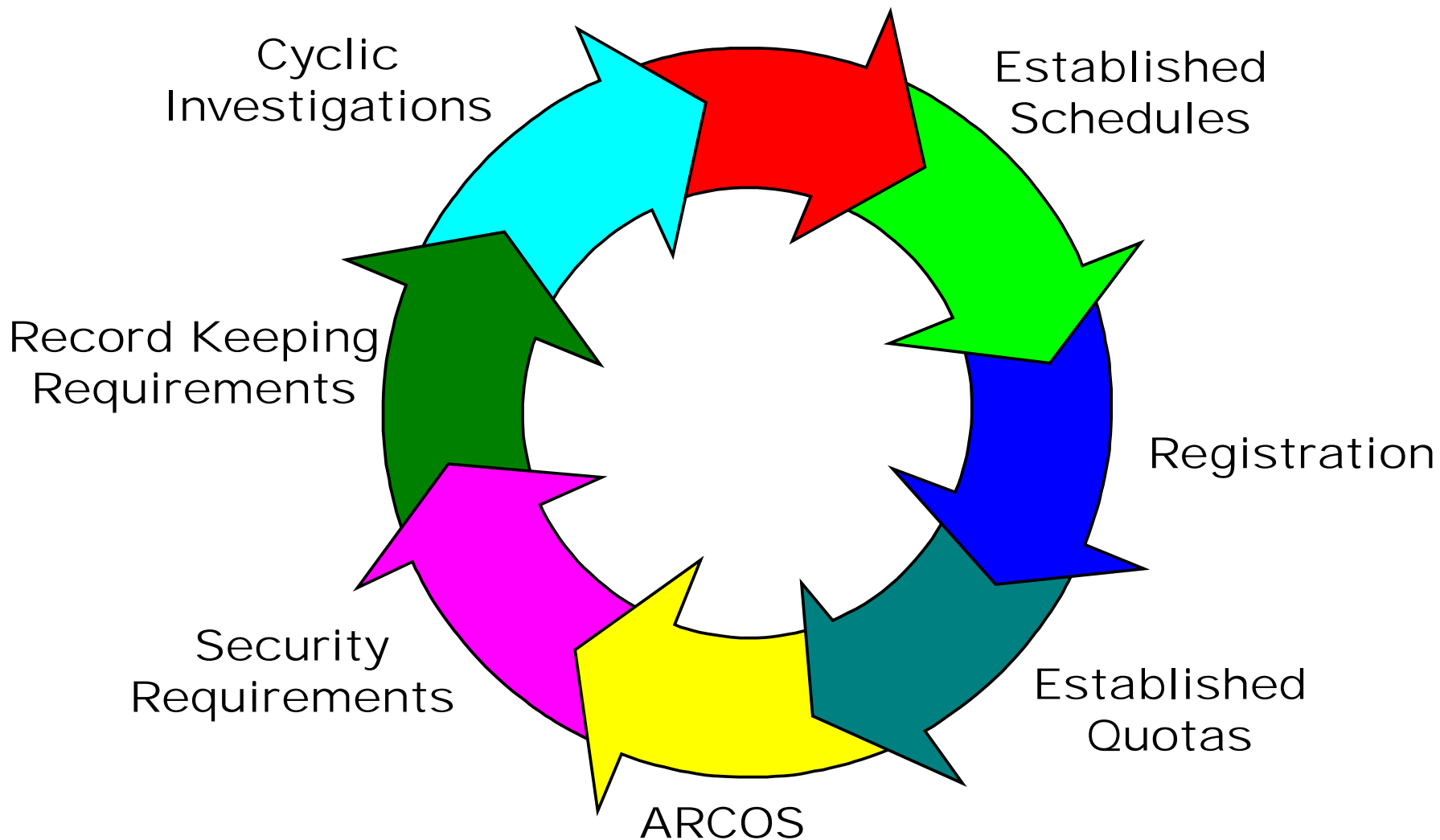
Research/Analysis 9,428

Narcotic Treatment Programs 1,441

Patients (U.S. pop.) 332,182,887



Closed System of Distribution



Closed System of Distribution

The DEA is responsible for:

- the oversight of the system
- the integrity of the system
- the protection of the public health and safety



U.S. Drug Enforcement Administration
Office of Diversion Control

Legal Obligations: DEA Registrant



Compliance with the CSA

This presentation does not cover the totality of your obligations nor is it a substitute for your obligations as a DEA registrant under the Controlled Substances Act and its implementing regulations.

Compliance with the CSA

The information presented should not be considered new information. The substance of this presentation has been previously available and communicated through the Controlled Substances Act, its regulations, Federal Register Notices, DEA-sponsored conferences, correspondence from the DEA, and releases from the popular press, as well as your own sales data.

Effective Controls

- All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.
- In order to determine whether a registrant has provided [effective controls](#) against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the [physical security controls](#) and [operating procedures](#) necessary to [prevent diversion](#).

21 CFR § 1301.71(a)

Suspicious Orders

Non-practitioners of controlled substances

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

21 CFR § 1301.74(b)

Prescriptions

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

21 CFR § 1306.04(a)

United States v Moore 423 US 122 (1975)



CDC Guidelines for Prescribing Opioids for Chronic Pain

- Clinical Reminders:
 - Opioids are not first-line or routine therapy for chronic pain
 - Establish and measure goals for pain and function
 - Discuss benefits and risks and availability of nonopioid therapies with patient

CDC Guidelines for Prescribing Opioids for Chronic Pain

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed

CDC Guidelines for Prescribing Opioids for Chronic Pain

- Evaluate risk factors for opioid-related harms
- Check PDMP for higher dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

Corresponding Responsibility by Pharmacist

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

21 CFR § 1306.04(a)



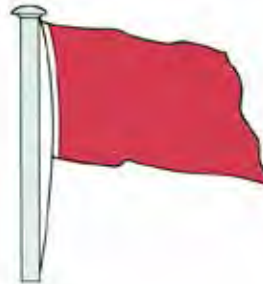
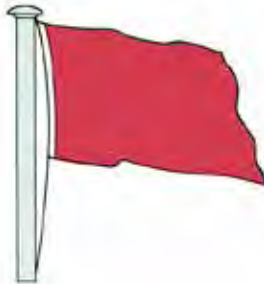
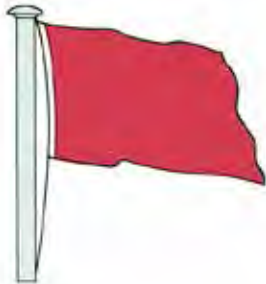
Corresponding Responsibility by Pharmacist

- A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate.
- When a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription!!!



You must KNOW YOUR CUSTOMERS.

What are some “Red Flags”?



Know Your Customers

Some factors to consider when distributing controlled substances:

§ Who is the purchaser?

§ Where are they going?

§ How many other distributors are involved?

§ Who are the downstream customers?

Know Your Customers

- Type and quantity of controlled substances being purchased
- Location and hours of operation
- Methods of payment utilized (cash, credit card, insurance)
- % controlled vs. % non-controlled

Know Your Customers

- What is the average monthly purchase for an average type of registrant for a particular controlled substance? For a particular geographical area?
- Does the requested purchase represent a quantity that far exceeds that average monthly purchase? Why?

Know Your Customers

- What do media reports say about the state or geographical area where the controlled substances are being sold?
- Is there a problem with controlled substances in that particular area? What controlled substances are involved?

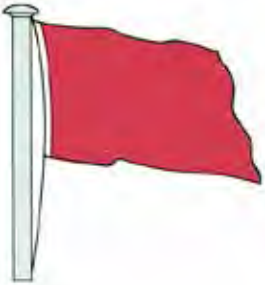
Know Your Customers

- Is a large portion of the CS prescriptions filled at a pharmacy for large quantities and paid for in cash or by credit card?
- Are the prescriptions mostly for opioids (hydrocodone, oxycodone), benzodiazepines (lorazepam, Ativan, diazepam), and muscle relaxers (Soma, Flexeril) prescribed together?



Know Your Customers

- Practitioner tells patients to fill their prescriptions at a specific pharmacy.
- The majority of the controlled substances prescriptions presented originated from the same practitioner.



Know Your Customers

- Many patients have identical prescriptions, (same drug, quantity, and strength) regardless of age, sex, or health.
- Patients of the same practitioner arrive at the pharmacy in groups with prescriptions for the same controlled substances.



United States V. Alvin Yee, M.D.

Dr. Alvin Yee



U.S. Drug Enforcement Administration
Office of Diversion Control



United States V. Alvin Yee, M.D.

MEDICAL OFFICE

Various Locations, Orange County, California



U.S. Drug Enforcement Administration
Office of Diversion Control



United States V. Alvin Yee, M.D.

Dr. Yee primarily met with his “patients” in Starbucks cafes throughout Orange County, California.

He would see up to a dozen patients each night between 7:00 and 11:00 p.m. and wrote these “patients” prescriptions, primarily for opiates, in exchange for cash.

Yee pled guilty to distributing millions of dollars in oxycodone, oxymorphone, hydrocodone, hydromorphone, Adderall® and alprazolam outside the course of professional practice and without a legitimate medical purpose.



United States V. Alvin Yee, M.D.

CURES Data (PMP)

During a one-year time period, Yee wrote prescriptions for a total of 876,222 dosage units of all medications combined.

52% of all prescriptions (458,056 dosage units) written by Yee were for oxycodone (92%-30mg) during the one-year period.

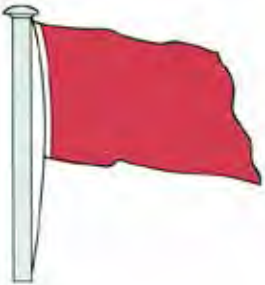
96% - oxycodone, hydrocodone, alprazolam, hydromorphone, and oxymorphone.

Almost half of Yee's patients were 25 and under.



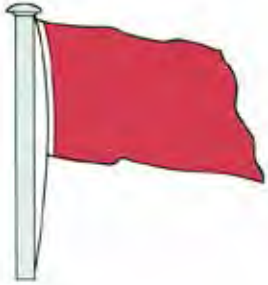
Know Your Customers

- Patients traveling great distances
- Prescriptions are pre-printed with the same diagnosis code
- Prescriptions are pre-printed with the same controlled substance



Know Your Customers

- Are there security guards on the premises? Why?
- Is there a line of people waiting to get into the place?
- Are there pain clinics in the area? How many? Is the pharmacy inside a pain clinic?





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Know Your Customers

The listed examples of “Red Flags” should not be considered all-inclusive. Each customer and situation should be looked at independently.

Reports: Non-Practitioners

21 CFR § 1301.74(b):

- The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances.
- The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant.

Know Your Customers

- Document your research
- Update regularly

Suspicious Orders

21 CFR § 1301.74(b)

- Orders of unusual size
- Orders deviating substantially from a normal pattern
- Orders of unusual frequency

These criteria are disjunctive (they can stand alone or together).

Suspicious Orders

Reporting of a suspicious order to the DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion.

Suspicious Orders

The responsibility for making the decision to ship or not to ship rests with the supplier.

Once a Suspicious Order is identified by the supplier the order must not be shipped.

Suspicious Orders

The DEA will no longer accept
“Excessive” Purchase Reports.

“Excessive” purchases were reported
after the order had been filled.

Reporting Thefts and Losses

- 21 CFR § 1301.74(c)
- Initial report in writing to local DEA office within one business day of discovery
- Complete DEA-106 form
- In-transit losses reported by shipper unless signed for by recipient

Reporting Thefts and Losses

- DEA-106 form on-line at www.dea diversion.usdoj.gov
- Must include NDC numbers
- Please try not to use “other” (may not be an option in future)

Closed System of Distribution

When a registrant fails to adhere to its responsibilities, those violations represent a danger to the public and jeopardize the closed system of distribution.



The DEA Response



Scheduled Investigations

- Increase in the number of DEA registrants that are required to be investigated to ensure compliance with the Controlled Substances Act and its implementing regulations
- Increase in the frequency of the regulatory investigations
- Verification investigations of customers and suppliers

DEA Legal Recourse

Ø Administrative

Immediate Suspension Order (ISO)

Memorandum of Agreement (MOA)

Order to Show Cause (OTSC)

Ø Civil

Fines

Ø Criminal

Arrests

Criminal fines



Administrative Actions

Distributors only

(January 1, 2007, to March 15, 2016):

• Letters of Admonition	414
• Memoranda of Agreement	37
• Administrative Hearings	11
• Surrenders for Cause	49
• Immediate Suspension	15
• Order to Show Cause Issued	19

Administrative Actions

Manufacturers only

(January 1, 2007, to March 15, 2016):

• Letters of Admonition	301
• Memoranda of Agreement	23
• Administrative Hearings	9
• Surrenders for Cause	27
• Immediate Suspension	2
• Order to Show Cause Issued	9

Distributor & Manufacturer cited Violations from Scheduled Investigations

- Failure to report to ARCOS
- Failure to report Theft and Loss
- Failure to maintain complete and accurate records
- Failure to document transfers between registrants
- Failure to account for losses
- Failure to account for samples

Distributor & Manufacturer cited Violations from Scheduled Investigations

- Failure to record date of receipt (222)
- Failure to maintain records separately
- Failure to execute a Power of Attorney for signing Order Forms
- No Biennial Inventory
- Procuring and manufacturing PSE without quota

Distributor & Manufacturer cited Violations from Scheduled Investigations

- **Common Security violations:**
- Making changes without notifying DEA
- No contact switch
- Storing none CS in CS vault without approval from DEA
- Failure to set up a system to detect suspicious orders

Civil Action - Distributor Registrants

- January 1, 2007 – March 15, 2016
- Civil action against 36 distributor registrations:
 - Conspiracy: Sold to doctor knowing doctor was selling to addicts
 - Did not report suspicious orders; did not use “due diligence” to “know its customers”
 - Did not maintain effective controls against diversion

Civil Action - Manufacturer Registrants

- January 1, 2007 – March 15, 2016
- Civil action against 17 manufacturer registrations:
 - Over \$2 million in civil fines

DEA Registrant Initiatives

Distributor Initiative

Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances

Briefings to **95** firms with **305** registrations

DEA Registrant Initiatives

Pharmacy Diversion Awareness Conference

This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity

Completed PDACs Attendance

FY-2011

1-Cincinnati, OH 9/17-18/11

FY-2011 Total Attendance

FY-2012

2-WPB, FL 3/17-18/12

3-Atlanta, GA 6/2-3/12

4-Houston, TX 9/8-9/12

5-Long Island, NY 9/15-16/12

FY-2012 Total Attendance

FY-2013

6-Indianapolis, IN 12/8-9/12

7-Albuquerque, NM 3/2-3/13

8-Detroit, MI 5/4-5/13

9-Chicago, IL 6/22-23/13

10-Portland, OR 7/13-14/13

11-Baton Rouge, LA 8/3-4/13

12A-San Diego, CA 8/16-17/13

12B-San Jose, CA 8/18-19/13

13-Boston, MA 9/21-22/13

FY-2013 Total Attendance

FY-2014

14-Louisville, KY 11/16-17/13

15-Charlotte, NC 2/8-9/14

16-Knoxville, TN 3/22-23/14

17-St. Louis, MO 4/5-6/14

18-Philadelphia, PA 7/12-13/14

19-Denver, CO 8/2-3/14

20-SLC, UT 8/23-24/14

21-Phoenix, AZ 9/13-14/14

FY-2014 Total Attendance

FY-2015

22-Las Vegas, NV 2/7-8/15

23-Birmingham, AL 3/28-29/15

24-Norfolk, VA 5/30-31/15

25-Oklahoma City 6/27-28/15

26-Milwaukee, WI 7/25-26/15

27-Seattle, WA 8/8-8/9/15

28-Portland, ME 9/12-9/13/15

FY-2015 Total Attendance

FY-2016

29-Pittsburgh, PA 12/10-11/15

30-Jackson, MS 1/9-10/16

31-Charleston, WV 2/27-28/16

32-Wilmington, DE 3/19-20/16

33-Towson, MD 4/17-4/18/16

Total Attendance To Date

75

75

1,192

328

518

391

2,429

137

284

643

321

242

259

353

434

275

2,948

149

513

246

224

276

174

355

259

2,196

193

296

410

253

114

210

94

1,570

196

185

245

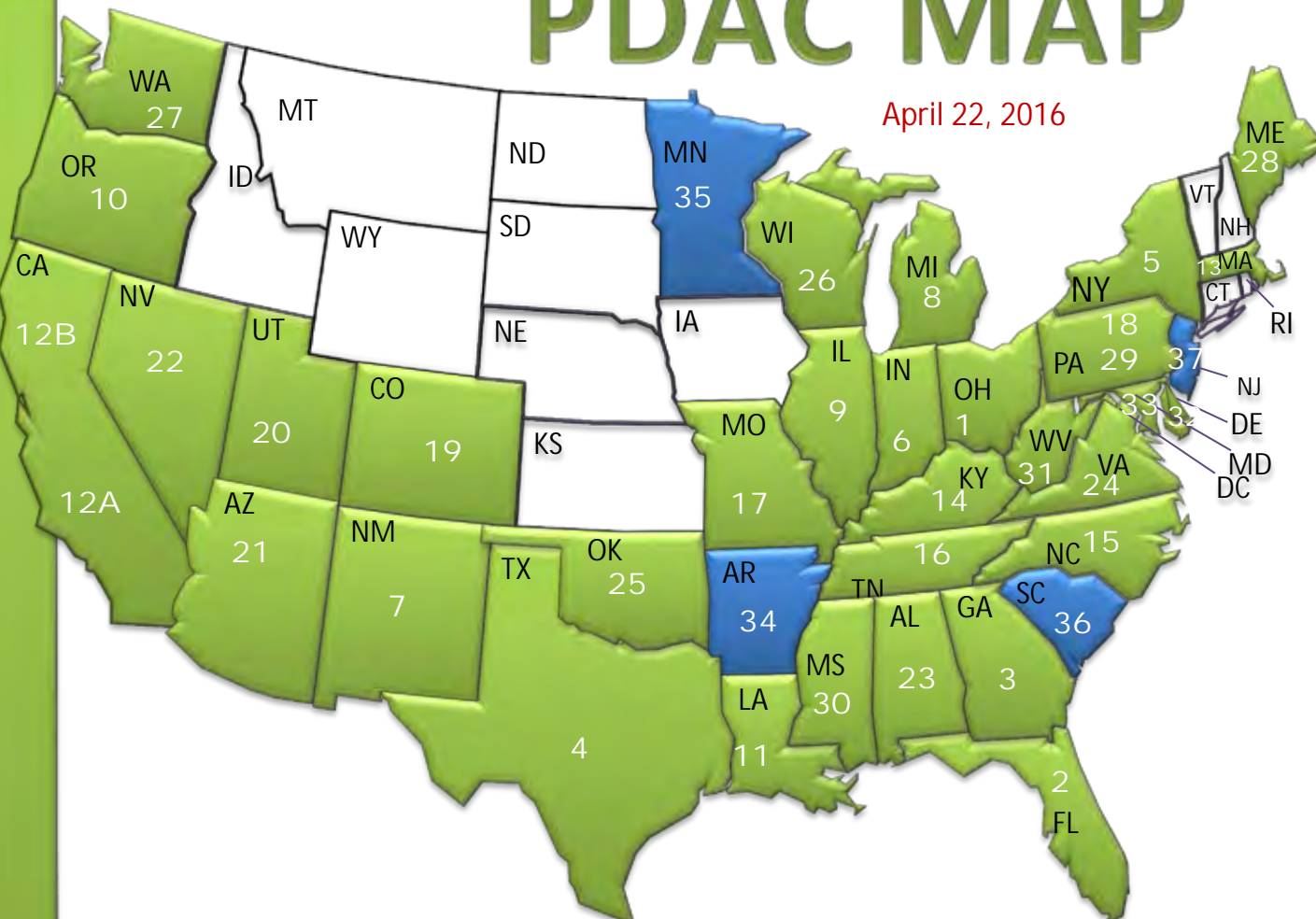
111

442

10,397

PDAC MAP

April 22, 2016



Proposed FY-2016 PDACs

34-Little Rock, Arkansas - June 12 & 13, 2016

35-Minneapolis/St. Paul, Minnesota - July 9 & 10, 2016

36-Charleston, South Carolina - August 2016

37-New Brunswick, New Jersey - September 2016

32 STATES

68 PDAC CONFERENCES

Completed PDACs
 Proposed PDACs

PDAC Issues Raised

- Pharmacies (chain & independent) are still being 'cut-off' from their wholesalers (thresholds)
- Effecting patient care
- Chain pharmacies are declining narcotic prescriptions, but taking the patients other prescriptions

PDAC Issues Raised

- Independent pharmacies are being presented with 'turn away' narcotic prescriptions reflecting in increase of their opioid purchases---wholesaler cutting them off
- Independents are requiring patient to bring all prescriptions to them so they can safely assess all medications patient is on.



Drug Enforcement Administration

360 Degree Strategy





Community Partnerships



- DEA recognizes we cannot arrest our way out of the drug problem – our goal is lasting success in the communities we serve.
- Education and Prevention are key elements for a true 360 Strategy.
- Law enforcement operations provide an opportunity for community empowerment and a jumping off point for education and prevention efforts.

DEA Registrant Initiatives

- The Federation of State Medical Boards (FSMB) promotes excellence in medical practice, licensure, and regulation on behalf of 70 state medical and osteopathic Boards across the country in their protection of the public
- DEA and FSMB are currently working on developing strategies to [work more effectively and jointly](#) on indiscriminate prescriber investigations in order to facilitate the administrative process to take action against those that are a threat to the public health and welfare quickly, and at the same time not jeopardize a criminal investigation

DEA Registrant Initiatives

“Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances”

- Represents the medical, pharmacist, and supply chain spectrum highlighting the challenges and “red flag” warning signs related to prescribing and dispensing controlled substance prescriptions
- The goal was to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny
- NABP along with 10 national associations and 6 major pharmaceutical firms were the coalition of stakeholders of this document.



National Take Back Initiative

April 30, 2016

Got Drugs?

Turn in your
unused or expired
medication for safe disposal

Saturday, April 30, 2016

Click here
for a collection
site near you.

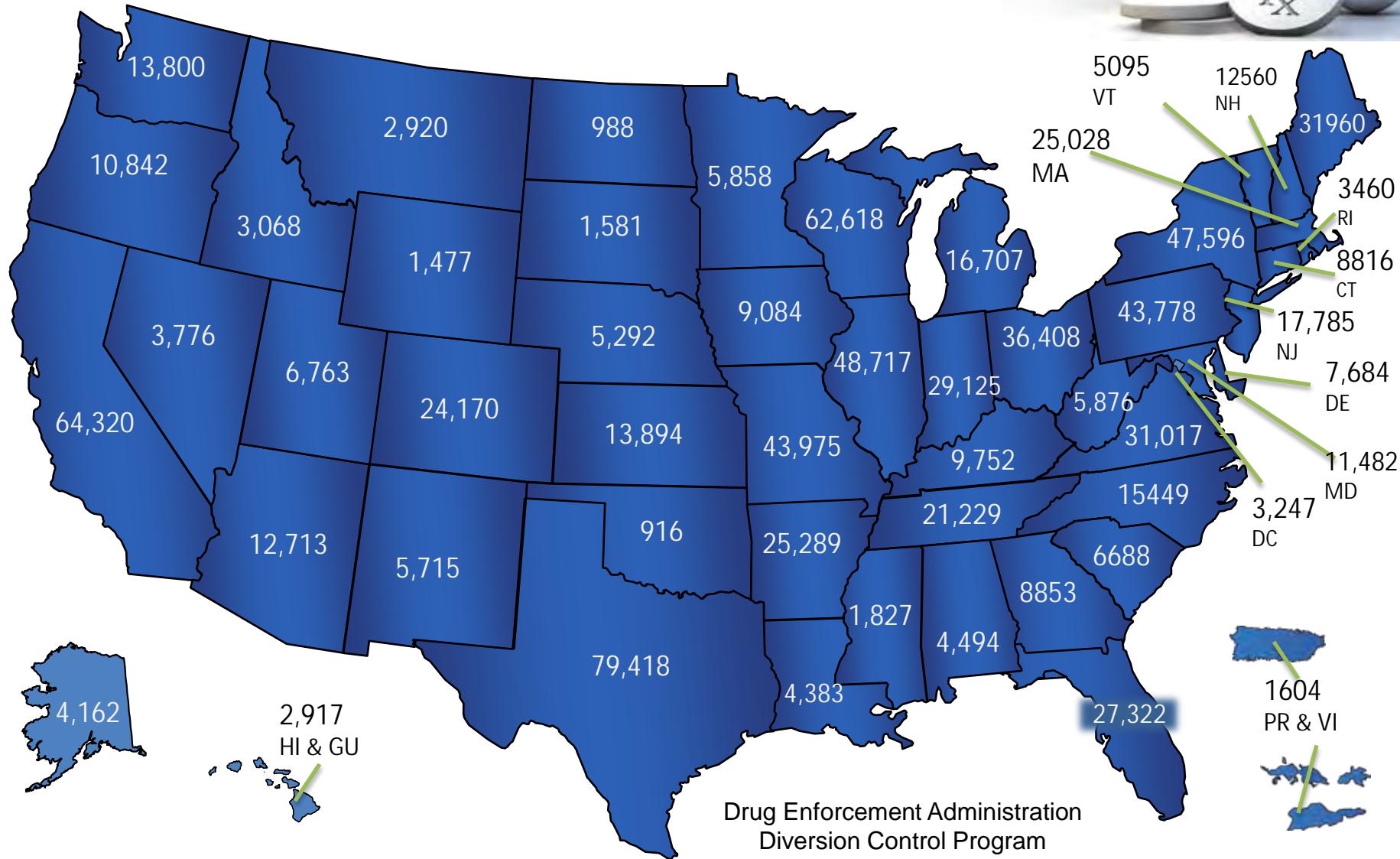


10:00 AM – 2:00 PM

U.S. Drug Enforcement Administration
Office of Diversion Control

11th National Take Back Day: **April 30, 2016**

Total Weight Collected (pounds): 893,498 (447 Tons)

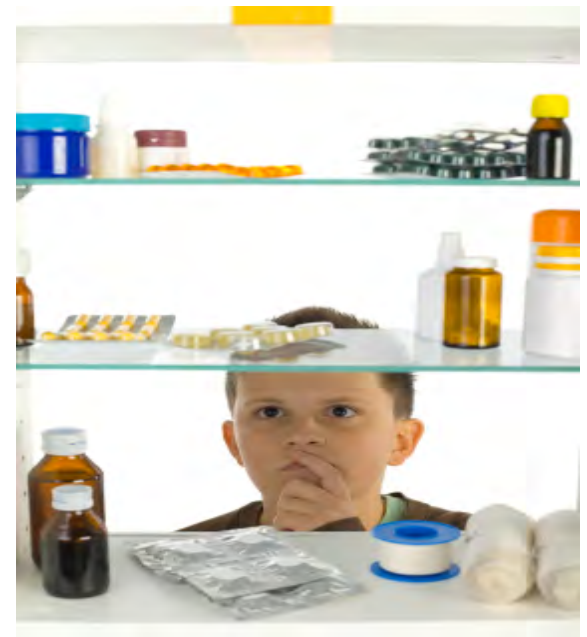


Secure and Responsible Drug Disposal Act of 2010



Secure and Responsible Drug Disposal Act of 2010

- ü Ultimate users now have more locations where they can securely, safely, responsibly, and conveniently dispose of their unwanted pharmaceutical controlled substances.
- ü Expected benefit to the public by:
 - Decreasing the supply of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
 - Protecting the environment from potentially harmful contaminants by providing alternate means of disposal for ultimate users.



Ultimate User

Ultimate user means as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.”

21 USC § 802(27)

Ultimate user methods of destruction prior to Disposal rule:

- ü Disposal in Trash (ONDCP method); or
- ü Flushing (FDA opioids and select CSs)
- ü National Take-back Event (DEA)
- ü Transfer to Law Enforcement
- ü (Police Station Receptacles or local Take-back events)
- ü DEA

Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner

21 USC § 822(f) & (g)

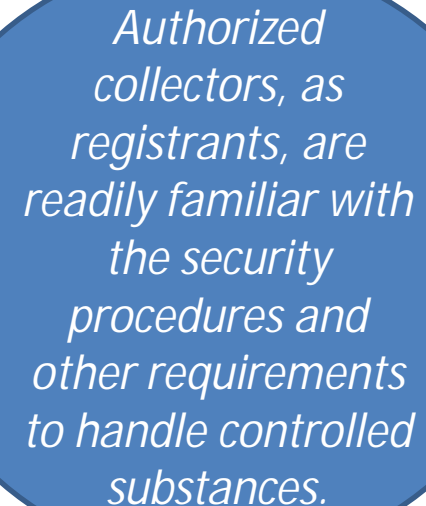
- Participation is voluntary

21 USC § 822(g)(2)

- Registrants authorized to collect:

- Ø Manufacturers
- Ø **Distributors**
- Ø Reverse Distributors
- Ø Narcotic Treatment Programs
- Ø Hospitals/clinics with an on-site pharmacy
- Ø Retail Pharmacies

21 CFR § 1317.40



Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.

Secure and Responsible Drug Disposal Act of 2010

- Disposal rule eliminated existing 21 CFR § 1307.12 & 1307.21
- New part 1317 contains the requirements on:
 - disposal procedures;
 - registrant inventory
 - collected substances
 - collection of pharmaceutical controlled substances from ultimate users;
 - return and recall; and
 - destruction of controlled substances

Law Enforcement

- Law Enforcement may continue to conduct take-back events.
- Any person may partner with Law Enforcement.
- Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.
- Authorized collection receptacles and inner liners “should” be used.

21 CFR § 1317.35 and 1317.65



Registrant Disposal



Registrant Disposal - Inventory

Practitioner & Non-Practitioner may **dispose of inventory**

- Prompt on-site destruction
- Prompt delivery to **reverse distributor** by common or contract carrier or **reverse distributor pick-up**
- Return and recall : Prompt delivery by common or contract carrier or pick-up at the registered location

Practitioner may also request assistance from the SAC

Non-Practitioner may also transport by its own means

21 CFR § 1317.05(a) and (b)

DEA Form 41

- Form 41 shall be used to record the **destruction of all controlled substances, including controlled substances acquired from collectors.**
 - The Form 41 shall include the names and signatures of the two employees who witnessed the destruction.
 - Exceptions for DEA Form 41:
 - Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41
 - Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and

Collection



Collection

Collection means to receive a controlled substance for the purpose of destruction from an:

- Ultimate user,
- Person lawfully entitled to dispose of an ultimate user decedent's property, or
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

21 USC § 822(g)(3) & (4) and 21 CFR § 1300.01(b)



Design of Collection Receptacles

- Securely fastened to a permanent structure.
- Securely locked, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.
- Outer container must display a sign stating only Schedule II-V and non-controlled substances are acceptable substances.
- Schedule I controlled substances are not permitted to be collected

21 CFR § 1317.75(e)



Collection Receptacle Inner Liner

- ü Waterproof, tamper-evident, and tear-resistant.
- ü Removable and sealable upon removal without emptying or touching contents.
- ü Contents shall not be viewable from the outside when sealed (i.e., can't be transparent).
- ü Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.).
- ü Outside of liner shall have permanent, unique ID number.

Collection Receptacles

- Ø Ultimate users *shall* put the substances directly into the collection receptacle.
- Ø Controlled and non-controlled substances may be comingled.
- Ø Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Ø Registrants shall not dispose of stock or inventory in collection receptacles.

21 CFR § 1317.75(b) and (c)

Collection Receptacle Location

- Registered location – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
 - LTCF – located in secure area regularly monitored by LTCF employees.
 - Hospital/clinic – located in an area regularly monitored by employees---not in proximity of where emergency or urgent care is provided.
 - NTP – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)

Mail-Back Program

Requirements of mail-back program

Ø Only lawfully possessed schedules II-V controlled substances may be collected

Ø Controlled and non-controlled substances may be collected together

Ø Must have method of on-site destruction

21 CFR § 1317.70 (b)

DEA Registrant who sells mail-back packages for another registrant is **NOT** required to modify registration as a collector

Miscellaneous Topics



Ensuring Patient Access and Effective Drug Enforcement Act of 2016

- ü Law in effect.

- ü DEA promulgated to write regulations.

DEA 222 Change to Mailing Address

- Originally the mailing address consisted of five lines: first line for name; second line for additional company information; third and fourth lines for address; and the fifth line for city, state, and zip code.
- To implement mailing efficiencies with the U.S. Postal Service, the mailing address portion was changed to enable the USPS to view the bar code through the window of the envelope. To accomplish this, DEA had to remove the second line.
-

DEA 222 Change to Mailing Address

- It has been brought to our attention this action has caused some confusion and suppliers were questioning the validity of the DEA order form.
- To quickly remedy the situation, DEA will place the second line (additional company information) right next to the first line (name). Unfortunately this action may result in truncated additional company information.

Questions?





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U.S. Drug Enforcement Administration
Office of Diversion Control